

REMARKS

Upon entry of the amendments, claims 1-31 and 44 are pending in this application. Claim 43 has been cancelled. By the amendments, Applicant does not acquiesce to the propriety of any of the Examiner's rejections and does not disclaim any subject matter to which Applicant is entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997). Further, Applicant reserves the right to prosecute the subject matter of any canceled claim in one or more continuation, continuation-in-part, or divisional applications.

The Rejection Under 35 U.S.C. § 103(a) Should Be Withdrawn

Claims 1, 2, 4, 5, 7-10, 12-18, 20-23 and 44 stand rejected as unpatentable under 35 U.S.C. § 103(a) over United States Patent No. 5,635,517 to Muller et al. ("Muller"). Applicants respectfully traverse.

The USPTO bears the burden of establishing a *prima facie* case of obviousness under 35 U.S.C. § 103. *In re Deuel*, 51 F.3d 1552, 1557 (Fed. Cir. 1995); *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993). To establish a *prima facie* case of obviousness, the USPTO must first show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, the USPTO must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an applicant's disclosure. Third, the USPTO must show that the prior art teaches or suggests all the claim limitations. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991).

Applicant teaches and claims, *inter alia*, a variety of methods of treating and/or preventing and/or inhibiting atherosclerosis and/or restenosis in a mammal using an effective amount of a variety of TNF- α inhibitors.

Applicant notes that it has not been established where or how Muller teaches or suggests all of the limitations of independent claims 1, 2, 3, 17, 18, and 19 (and all claims dependent therefrom). The Examiner admits that Muller does not expressly relate to "utilizing [an effective amount of a TNF-alpha inhibitor] for the prevention of atherosclerosis or restenosis." Paper No. 12 at page 6. The Examiner also fails to establish where or how Muller teaches or suggests methods of inhibiting restenosis. For these reasons alone, the pending rejections of independent claims 1, 2, 3, 17, 18, and 19 (and all claims dependent therefrom) based upon alleged obviousness must be withdrawn.

Further, it is not been established where or how Muller teaches or suggests all of the limitations of independent claims 4, 5, and 6 (and all claims dependent therefrom). Specifically, for example, the Examiner has not established where or how Muller teaches or suggests any methods of treating atherosclerosis, let alone the methods of independent claims 4, 5, and 6 (and all claims dependent therefrom). As such, the pending rejections of independent claims 4, 5, and 6 (and all claims dependent therefrom) based upon alleged obviousness must be withdrawn.

The Examiner contends that the alleged disclosure of congestive heart failure in Muller would make it obvious to one of skill in the art to modify Muller for the treatment and/or prevention of atherosclerosis and restenosis. *Id.* at pages 2-3, 6. Applicant respectfully disagrees; congestive heart failure, atherosclerosis and restenosis are each distinct diseases with distinct etiologies and are each treated with different therapies. Indeed, the Examiner acknowledges on page 2 of the Final Office Action that “all three conditions bare some differences in etymology.”

Further, while the Examiner contends that “[c]ongestive heart failure is related to the group of ischemic heart diseases that also include [*sic*] atherosclerosis and coronary artery disease” (Paper No. 12 at pages 3, 6), the Examiner has provided to Applicant no reference to support this contention. Section 2144.03 of the Manual of Patent Examining Procedure (M.P.E.P.) demands that if the Examiner is relying on personal knowledge to support the finding of what is known in the art, the Examiner must provide an affidavit or declaration or reference setting forth specific factual statements and explanation to support the finding. As the Examiner has not provided a single reference or an affidavit to support her contention that congestive heart failure is related to the group of ischemic heart diseases, Applicant respectfully invites Examiner to provide such a reference or file an Affidavit pursuant to 37 C.F.R. § 1.104(d)(2). In the absence of such a reference or affidavit which is, of course, subject to rebuttal by Applicant, the mere contention of the part of the Examiner that the compounds of Muller can be used to treat congestive heart failure does not provide adequate support for the Examiner’s rejection over Muller of Applicant’s claims drawn to novel methods of treating and/or preventing and/or inhibiting atherosclerosis and/or restenosis in a mammal.

Additionally, the Examiner’s arguments appear to reflect a lapse into tactics long proscribed by Federal Circuit precedent. Specifically, the Examiner suggests that it would have been obvious to one of ordinary skill to try to use compounds of Muller with respect to atherosclerosis and restenosis. Paper No. 12 at pages 2-3. The Examiner also

alleges that it would have been obvious for one of ordinary skill in the art to try to use compounds of Muller in a pharmaceutical regimen that would decrease or mitigate factors that are known to cause damage to muscle fibers. *Id.* at pages 5-6. As the Examiner knows, "obvious to try" is not a proper legal standard to apply in the context of a rejection based upon alleged obviousness. *See, e.g., In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1599 (Fed. Cir. 1988).

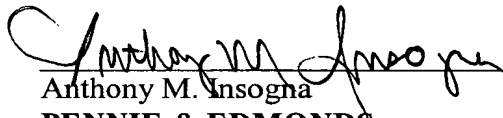
Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 1, 2, 4, 5, 7-10, 12-18, 20-23 and 44 under 35 U.S.C. § 103(a).

CONCLUSION

Applicant respectfully requests that the above remarks and accompanying documents be entered in the present application file. An early allowance of the present application is respectfully requested.

Respectfully submitted,

Date: July 18, 2003


Anthony M. Insogna 35,203
(Reg. No.)
PENNIE & EDMONDS LLP
1155 Avenue of the Americas
New York, New York 10036-2711
(212) 790-9090